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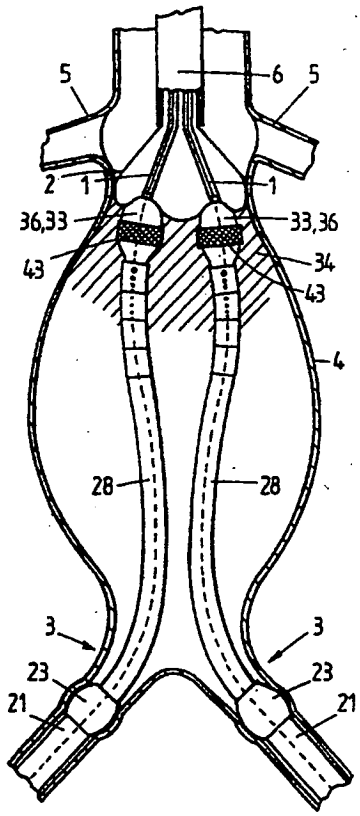
(54) Title: ARRANGEMENT FOR THE ENDOVASCULAR REPAIR OF A BLOOD VESSEL SECTION

(57) Abstract

The present invention relates to an arrangement and a method for the endovascular repair of a blood vessel section, in particular an infrarenal abdominal aortic aneurysm (4). The arrangement comprises means for isolating said section, including distal occluding means (6) for occluding the blood vessel (2) at a distal end of said section and proximal occluding means (21) for occluding the blood vessel at a proximal end thereof; a blood channel forming catheter (33) arranged for being inserted into said section to define a blood channel within said section between said proximal and distal occluding means (6, 21); and means (28) for injecting an occluding agent producing a solid mass (34) in said section around said blood channel forming catheter (33) to form a new blood wall around said blood channel.



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"Arrangement for the endovascular repair of a blood vessel section"

The present invention relates to an arrangement for the endovascular repair of a blood vessel section, wherein a new blood channel wall is formed in this section. The particular blood vessel section may need repair for various reasons, for example as a result of aneurysmal disease, ruptured aneurysmal disease, occlusive disease (repair needed after dilatation of the occluded section) or blood vessel occlusions of any ethiology, traumatic lesions, AV fistula's, etc. Although the arrangement according to the present invention may be applicable to all of these disorders, it will be described hereinafter mainly with reference to the repair of a blood vessel aneurysm, in particular an infra-renal abdominal aortic aneurysm.

The infrarenal abdominal aorta is prone to aneurysmal dilation between the renal and iliac arteries or even with extension more distally, and is in due course unable to withstand arterial pressures so that dilation tends to progress to a point where rupture is likely. Highly invasive conventional repair such as described in US-A-3,657,744 is a major surgical intervention with high morbidity and even sometimes mortality. The invention, however, is not limited to aortic aneurysm repair and has applications in a variety of situations in which corporeal lumen repair is required.

Endovascular repair of abdominal aortic aneurysm avoids much of the morbidity and mortality associated with conventional surgery. In the known endovascular repair techniques, disclosed for example in US-A-4,140,126 (Choudhury); US-A-4,512,338 (Balko et al);

US-A-4,787,899 (Lazarus); EP-A-0 461 791 (Barone, Parodi, Palmaz); etc., an intraluminal graft/stent is positioned in the aneurysm. This graft/stent is either self-expandable or balloon expandable and is expanded more particularly in a non-dilated part of the blood vessel at the proximal and distal sides of the aneurysm in order to be fixed thereto. Most patients with abdominal aortic aneurysm lack a segment of non-dilated aorta suitable for attachment of the downstream (caudal) end of a straight (single-lumen) endovascular graft. In these patients a more secure outflow is provided by attaching the two caudal ends of a bifurcated graft to the iliac arteries involving however additional problems in correctly positioning and optionally attaching these two caudal ends.

A first problem inherent to the know techniques referred to hereinabove is indeed that it is difficult to position the graft accurately in the blood vessel, in particular the upstream end thereof which has to be expanded in the non-dilated aorta segment or neck between the renal arteries and the aortic aneurysm, because the length of this neck is usually rather short and because, once expanded, the graft can no longer be replaced. In case of an incorrect positioning of the graft, a conversion to open surgical repair would thus still be required.

A more important problem related to these known techniques is that thrombus formation should occur around the graft in the aneurysm so as to fill or exclude it and so to avoid any flow of blood and thus any blood pressure in the excluded aneurysm since this may still lead to rupture of the aneurysm. In practice, this is a very realistic situation in view of the fact that the proximal neck of the aneurysm is usually rather irregular with calcifications and mural trombusmaterial or may in time dilate further creating possible leakage between the wall of the blood vessel and the extremity of the graft expanded therein. Another important problem is the persistence of collateral blood vessels ending in the aneurysm and thus still feeding into the aneurysm with subsequent

rupture possibility. A further problem is the existing risk of dislodgement of the graft from the usually short proximal neck of the aneurysm with the further dilatation of this neck.

US-A-5,156,620 (Pigott) discloses also a graft/stent for intraluminal repair of an abdominal aortic aneurysm comprising more particularly a double wall to define a radially expandable chamber along the graft destined to be filled with a plastic material. A drawback of this known graft is that the dimensions thereof have to correspond to the dimensions of the aneurysm so that the aneurysm has to be measured in advance and the graft itself has to be made to size. Of course, this requires additional investigations and time which may be at a premium in case an urgent intervention is required. This is also true for several other stent grafts which are momentarily in clinical use.

An object of the present invention is to provide a new arrangement for the endovascular repair of a blood vessel section, in particular an aneurysm or an otherwise damaged or deformed section of a blood vessel, which enables to avoid the drawbacks of the known techniques set forth hereinabove and which especially enables to realise a reliable exclusion of an aneurysm in a relatively easy way.

To this end, the arrangement according to the present invention is characterized in that it comprises:

- means for isolating said section, including distal occluding means for occluding the blood vessel at a distal end of said section and proximal occluding means for occluding the blood vessel at a proximal end thereof;
- a blood channel forming catheter arranged for being inserted into said section to define a blood channel within said section between said proximal and distal occluding means; and

- means for injecting an occluding agent producing a solid mass in said section around said blood channel forming catheter to form said new blood wall around said blood channel.

Due to the fact that the occluding agent is injected in the section, in particular in the aneurysm itself, the solid mass formed upon reaction of the occluding agent will fit accurately therein thus considerably reducing the risks of endoleaks. Moreover, the new blood channel cannot dislodge from the adjacent ends of the blood vessel. An important advantage of the arrangement according to the invention is further that the blood vessel section which has to be repaired has not necessarily to be measured in advance hence enabling a quick intervention, for example in case of rupture of the aneurysm.

Injection of an occluding agent in an aneurysm is already known per se from EP-A-0 664 104, however, not for forming a new blood channel or blood channel wall but for entirely occluding a peripheral aneurysm or vessel through an opening in the side wall of a main blood vessel leading to the peripheral aneurysm. The balloon catheter disclosed in this European patent application is in particular not provided for defining a new blood channel in the aneurysm but instead for sealing the main vessel side and lumen from the vessel opening into the peripheral aneurysm.

An important advantage of the arrangement according to the invention is that it does not necessarily require the use of an endograft for repairing the blood vessel. In a particular embodiment of the arrangement according to the invention, said blood channel forming catheter may, however, be arranged for carrying on its outer surface an endograft, in particular a balloon or self-expandable graft, and for disposing this endograft between said proximal and distal occluding means in said section to form part of the new wall which is to be formed, in particular the inside thereof.

Since the endograft will be embedded in the solid mass formed by reaction of the occluding agent in the aneurysm, it cannot dislodge and its dimensions, especially its width, have not to be adjusted in advance to the dimensions of the aneurysm but the graft can be cut for example to the desired length during the procedure itself when it is clear how long the graft should be. A further important advantage is that even in case the aortic aneurysm extends down to the iliac arteries, no bifurcated graft is required but instead use can simply be made of two grafts which are embedded parallel to one another in the solid mass formed by the occluding agent in the aneurysm.

In a preferred embodiment of the arrangement according to the invention, said means for injecting an occluding agent comprise an injection sheath which is insertable through said distal occluding means and which has a lumen arranged to slidably house said blood channel forming catheter.

Other details and advantages of the present invention will become apparent from the following description of some particular embodiments of the arrangement for the endovascular repair of a blood vessel section according to the invention. This description is, however, only given by way of example and is not intended to limit the scope of the invention. The reference numerals relate to the annexed drawings wherein:

Figures 1 to 3 are partial sectional views of an abdominal aortic aneurysm with extension into the iliac bifurcation illustrating successive steps in the repair of these aneurysms by means of an arrangement according to the present invention;

Figures 4 and 5 are partial side elevational views, on a larger scale and partly in longitudinal section, of the distal portion of the occlusion catheter of the arrangement shown in Figures 1 and 2 which is inserted upstream through the iliac arteries, respectively in the position

shown in these figures, more particularly in a partially and entirely inflated state of the new blood channel forming catheter;

Figure 6 is a longitudinal section of the proximal part of the occlusion catheter shown in Figure 5;

Figure 7 is a partial side elevational view, also on a larger scale and partly in longitudinal section, of the distal portion of the occlusion catheter of the arrangement shown in Figures 1 and 2 which is inserted downstream in the aorta to occlude the proximal neck of the aneurysm.

Figure 8 is a cross-section according to line VIII-VIII in Figure 7;

Figure 9 is a longitudinal section of the proximal part of the occlusion catheter shown in Figures 7 and 8;

Figures 10 and 11 are views similar to Figures 7 and 8 respectively but relating to an alternative embodiment;

Figure 12 is a view similar to Figure 4 but relating to an alternative embodiment;

Figure 13 is a schematic side elevational view of a variant embodiment of the proximal occlusion catheter;

Figures 14 and 15 are cross-sectional views through lines XIV-XIV and XV-XV in Figure 13;

Figure 16 is a side elevational view of a variant embodiment of the occlusion balloon of the proximal occlusion catheter shown in Figure 13;

Figure 17 is a cross-sectional view according to line XVII-XVII in Figure 16;

Figure 18 is a schematic side elevational view of a variant embodiment of the distal occlusion catheter;

Figure 19 is a schematic side elevational view, partly in longitudinal section, of a variant embodiment of the means for injecting the occluding agent; and

Figure 20 is a cross-sectional view through line XX-XX in Figure 18.

In these figures, the same reference numerals have been used to designate the same or analogous elements.

The arrangement according to a first embodiment of the invention shown in Figures 1 to 9 is usually disposed in the blood vessel by means of a guide wire 1, in this embodiment even by means of two guide wires 1. How to insert these guide wires 1, in particular through a sub-clavean or brachial artery acess,and down through the aorta 2 and the iliac arteries 3 and out of the left and right femoral arteries, is a technique which is known per se and which will consequently not be described herein in further detail.

Over the guide wires 1 are first of all inserted means for occluding the blood vessel, in this case the aorta 2, at a proximal end of the aneurysm 4, more particularly at the non-dilated portion of the aorta 2 between the aneurysm 4 and the renal arteries 5. These proximal occluding means are formed by a first occlusion catheter 6, shown on a larger scale in Figures 7-9, and are of a special design, as described hereinafter, in view of occluding the usually short non-dilated proximal part or neck of the aorta 2 without occluding the renal arteries 5.

In the embodiment shown in Figures 7-9, the proximal occluding means or first occlusion catheter 6 comprises a reinforced outer sheath 7, an inner sheath 8, two guide wire tubes or lumens 9 disposed within the inner sheath 8 and a number of inflatable balloon chambers 10, 11. The sheaths 7 and 8 and the tubes 9 are made of a flexible material, such as polyethylene, nylon, polyurethane, polyvinylchloride, teflon, optionally reinforced with a metal mesh to

obtain torque. At the proximal end of the first occlusion catheter 6, the inner sheath 8 projects out of the outer sheath 7, at least when inserting the catheter 6. Indeed, once inserted, the outer sheath 7 can be pulled back over a distance d so that the distal extremity 12 of the inner sheath 8 is released. This distal extremity 12 is either balloon-expandable, balloon-adjustable or even self-expandable and is afixed to the outer balloon 11 in a separate double layer covering and comprises a reinforcement in an inelastic material such as a web like structure of metal or inelastic synthetic fibres or in a foldable material limiting the outward expansion of the more distal portion thereof. This is achieved by the distance of release through the pull back of the outer sheath 7. The limitation of the outward expansion of the distal extremity 12 of the inner sheath 8 is especially important in case of a short neck of non-dilated aorta between the renal arteries 5 and the aneurysm 4 in order to be able to occlude the aorta without occluding the renal arteries 5 and to be able to adjust the diameter to that of the aorta section, more particularly by controlling the length of release of the inner sheath 8 out of the outer sheath 7. The kidneys are indeed very sensitive to an interruption of the blood supply. An important feature of the distal extremity 12 of the inner sheath 8 is further that it is impermeable to blood and that it forms a so-called "umbrella" occlusion structure so that no blood can pass therealong or through.

In the illustrated embodiment, the distal extremity 12 of the inner sheath 8 is self-expandable and balloon-adjustable or balloon-expandable and comprises a soft tip 46. The distal extremity 12, in particular the soft tip 46, is preferably glued or afixed to the balloon used to expand it so that, upon inflation of this balloon, the soft tip bends, whereby the risk of damaging the wall of the blood vessel is considerably reduced.

In order to expand the distal extremity 12 of the inner sheath 8 so as to occlude the proximal end of the aneurysm 4, the first occlusion catheter 6, shown in cross-section in Figure 8, comprises at its distal extremity four peripheral balloon chambers 11, disposed between the guide wire tubes 9 and the distal extremity 12, and one central balloon chamber 10 disposed between both guide wire tubes 9. In a variant embodiment, the peripheral balloon chambers 11 may comprise only two chambers or even only one chamber, preference being given however to four peripheral balloon chambers. These balloon chambers 11 extend either separately through the lumen of the inner sheath 8 to the proximal extremity of the catheter 6 or may be separated from one another, by partition walls 13, only at the distal extremity of the inner sheath 8. The central balloon chamber 10 normally extends separately through the inner sheath 8 and 12 to the proximal extremity thereof and may possibly also be divided by partition walls into two or more balloon chambers. The central balloon chamber 10 serves to spread the distal extremities of the guide wire tubes 9 and is either disposed between these tubes 9 or these latter tubes 9 are attached, in particular glued or welded, within the central balloon chamber 10 to the wall thereof.

An important feature of the balloon chambers 10 and 11 is that they project in a non-inflated situation considerably beyond the distal extremity of the guide wire tubes 9 and the edge of the inner sheath 8 and are covered by the outer sheath 7. After outer sheath 7 withdrawal and inflation of the balloon chambers 10 and 11, these still project, but less, beyond the extremity of the guide wire tubes 9 and the edge of inner sheath 8, so that they can co-operate more effectively with the blood channel forming catheter to be discussed hereinafter. During the introduction of the first occlusion catheter 6, the balloon chamber 10 and/or the balloon chambers 11 are preferably partially inflated to close off the distal extremity of this catheter 6. Preferably, these balloon

chambers 10 and/or 11 project moreover somewhat out of the outer sheath 7, and are partially inflated, so as to provide a softer balloon tip to make introduction of the catheter easier.

Referring to Figure 9, the first occlusion catheter 6 for occluding the proximal end of the aneurysm 4 comprises further at its proximal extremity two eyes 14 fixed to a flange 15 on the inner sheath 8 for being able to suture this inner sheath to the body, a flange 16 on the proximal edge of the outer sheath 7 for pulling this outer sheath back over the inner sheath 8, two valve fittings 17, 18 for connecting the inflatable balloon chambers 10, 11 to a source of pressurised fluid, preferably a liquid containing a diluted contrast medium, and two guide wire haemostatic valves 19, 20, mounted on the proximal extremities of the guide wire tubes 9.

At the other end of the aneurysm 4, i.e. at the distal end thereof, the blood vessel is also occluded by occluding means, more particularly by a second occlusion catheter 21 to be inserted either in a non-dilated aorta segment at the distal end of the aortic aneurysm, or in case the distal end of the aorta, and possibly also a portion of the iliac arteries, are dilated as shown in Figures 1 to 3, in a non-dilated or non-diseased portion of the iliac or femoral arteries. In this case, one needs of course two occlusion catheters 21 in order to isolate the aneurysm 4.

Each of the occlusion catheters 21, illustrated on a larger scale in Figures 4-6, comprises a first sheath 22 having at its distal extremity an expandable, inflatable occlusion balloon 23 provided thereon. This occlusion balloon 23 preferably extends right to the edge of the catheter 21 in order to be able to co-operate with the blood channel forming catheter as will be explained hereinafter. The first sheath 22 has a double wall, the annular lumen 24 formed thereby is in fluid communication with the interior of the occlusion balloon 23 and, at the proximal extremity of the sheath 22, with a valve fitting 25 arranged

to connect the occlusion balloon 23 to a source of pressurised fluid, preferably a liquid containing a diluted contrast medium. At its proximal extremity, the sheath 22 is moreover also provided with an eye 26 for rigidly fixing it by means of sutures to the body of the patient.

The central lumen 27 of the first sheath 22 provides a passageway, in particular through a haemostatic valve 61 on the proximal extremity of the sheath 22, for the introduction of means for injecting an occluding agent in the aneurysm 4 in order to form a new blood channel within the aneurysm, more particularly upon reaction of the occluding agent resulting in the formation of a solid mass in the aneurysm. Referring in particular to Figures 4, 5 and 6, these injection means comprise in particular an injection sheath 28 which is slidably disposed through the central lumen 27 of the first sheath 22 into the aneurysm 4 up to the vicinity of the first occlusion catheter 6. In the embodiment shown in the figures, the injection sheath 28 also has a double wall defining an annular lumen 29 for the delivery of the occluding agent into the aneurysm 4. At its proximal extremity, this lumen 29 is connected to an occluding agent inlet port 30. At its distal extremity, four longitudinal rows of occluding agent delivery openings 31 are provided in the outer wall of the injection sheath 28. The diameters of these openings 31 preferably decrease from the distal extremity of the injection sheath 28 towards the proximal extremity thereof in order to make sure the aneurysm 4 will be entirely filled with occluding agent during pull back as explained hereinafter.

Just like the first sheath 22, the injection sheath 28 has a central lumen 32 through which a blood channel forming catheter 33 can be inserted into the aneurysm 4. In the embodiment shown in Figures 1 to 6, this catheter 33 is pushed over the guide wire 1 with its distal extremity against the first occlusion catheter 6 to define a new blood channel within the aneurysm 4 between the proximal and distal occluding

means. The new blood channel itself will be formed upon reaction of the injected occluding agent to become a solid mass 34 around the blood channel forming catheter 33. The catheter 33 comprises at its proximal extremity a guide wire haemostatic valve 35.

In the preferred embodiment, shown in the figures, the blood channel forming catheter 33 comprises an expandable, inflatable portion, in particular a generally cylindrical balloon 36 which defines, in its expanded state, the new blood channel. The balloon 36 is arranged on a central guide wire tube 37 and extends through the lumen 32 of the injection sheath 28 down to the proximal extremity thereof where it is connected to a valve fitting 38 for connecting the balloon 36 to a source of pressurised fluid, preferable diluted contrast medium, which enables to visualise the balloon 36, or in other words the new blood channel will be formed, under fluoroscopic guidance after balloon expansion.

In order to repair the abdominal aortic aneurysm and iliac aneurysm shown in Figures 1 to 3 with the arrangement according to the invention shown in Figures 4 to 9, the first or proximal occlusion catheter 6 is first disposed and inflated in the non-dilated proximal neck of the aneurysm 4 in order to occlude this neck without preventing flow of blood into the renal arteries 5. Subsequently, the two distal occlusion catheters 21 are inserted over the guide wires which were delivered through the first occlusion catheter 6, providing a central lumen 27 for the introduction of the injection sheath 28 through which the blood channel forming catheter 33 is then introduced. By means of the guide wires 1, the blood channel forming catheter 33 is tensed and locked against the first occlusion catheter 6. In order to form the new blood channel, more particularly in order to exclude a portion of the aneurysm 4, an occluding agent is injected through the injection sheath 28 into the proximal portion of the aneurysm 4 (Figure 1). The injection sheath 28 is gradually withdrawn during the installation of the occluding agent and

through the first sheath 22 whilst the cylindrical balloon 36 of the blood channel forming catheter 33, which remains in place, is simultaneously inflated (Figure 2). Blood material which is still present in the aneurysm during occlusion agent installation is urged through the space between the first sheath 22 and the injection sheath 28 and through a venting hole 39 connected thereto out of the aneurysm 4. In Figure 4, the blood channel forming catheter 33 is shown in an initial state, corresponding to the state in Figure 1 whilst in Figure 5, the catheter 33 is shown nearly in the final state, corresponding to the state shown in Figure 2, wherein the injection sheath 28 has been withdrawn almost completely in the first sheath 22 and the balloon 36 on the catheter 33 is nearly entirely inflated. When the injection sheath 22 has been withdrawn completely and the balloon 36 on the blood channel forming catheter 33 is entirely inflated, the balloon 36 preferably engages the occlusion balloon 23 in order to obtain a smooth transition between the new blood channel wall which will be formed and the adjacent existing blood vessel wall which did not need repair. Once the occlusion agent has reacted to a solid mass 34, the balloons 23 and 36 are deflated and the entire distal occlusion catheters 21 and the proximal occlusion catheter 6, after deflation of balloons 10 and 11, are removed (Figure 3). Due to the particular balloon construction of the proximal occlusion catheter 6, a smooth funnel-shaped entrance 40 to the two new blood channels 41 is achieved.

In the above description of the preferred embodiment shown in Figures 1 to 9, no mention has yet been made of the aortic endografts 42 which may additionally be used and which have also been illustrated in the figures. The shown aortic endografts 42 comprise at their extremities or over their full length a balloon expandable or selfexpandable stent structure 43. The endografts 42 are initially disposed within the central lumen 32 of the injection sheath 28 over the

balloon portion 36 of the blood channel forming catheter 33. When withdrawing the injection sheath 28 whilst injecting the occluding agent, the endografts 42 remain in place and will after balloon dilatation thus define the inner wall of the newly formed blood channels 41. The same principle is also possible with a full length self-expandable endograft with the need for balloon tayloring after delivery or for a full length balloon expandable graft.

The occluding agent is preferably introduced as a liquid and hardens within the aneurysm chamber. In a first variation, the occluding agent may require a reactive catalyst to harden, and the injection sheath may be provided with a further lumen and injection openings adjacent to the first injection openings for separately introducing the catalyst. In a further variation, the occluding agent may react to radiation of a certain wavelength which is provided from an external source and introduced for example through the injection sheath and directed to the injected occluding agent to effect hardening thereof by a light conductor or optical fibre. Alternatively, the occluding agent may comprise a blood coagulating material.

With respect to specific materials which can be used as occluding agent, reference can be made to the materials disclosed in EP-A-0 664 104 which are included herein by way of reference. The disclosed occluding agents include more particularly cross-linked collagen implant fibrils which may be mixed with contrast media and chemical buffers of the types described in US-A-4,708,718. A liquid or paste collagen is available under the name HELIOSTAT. A further liquid thrombin mixture is available under the name THROMBOSTAT. Such thrombin and collagen including mixtures form an occluding cast by thrombus formation.

Other liquid, single component, occluding agents described in EP-A-0 664 104 include methyl cyanoacrylate adhesives or 2-

hydroxyethyl methylacrylate (HEMA) which set on contact with body fluids, e.g. of the type described in U.S.Patent No. 4,207,891 directed to occluding Fallopian tubes. In addition, liquid silicone rubber may be used.

As mentioned still in the same European patent application, solid, single component, occluding agents may also be used in solid fibrous or particulate form that may be delivered into the aneurysm to form a solid mass of thrombus. The occluding agent is effective to coagulate blood around the fibers or particles and to form the thrombus mass within the aneurysm to function as a solid occluding cast. Such occluding agents may also include one of the group of particulate compounds comprising polyvinyl alcohol (PVA), IVALON, and GELL FOAM which are reactive to blood to coagulate it on contact, as described by Purdy in "Pre-Operative Embolization of Cerebral Arteriovenous Malformations with Polyvinyl Alcohol Particles", AJNR 11:501-510, May/June, 1990.

Further, light reactive occluding agents are disclosed in EP-A-0 664 104 including urethane oligomer/(meth) acrylate monomer blends reactive to light in the ultraviolet range and particularly the compound Dymax 136-M which is reactive to ultraviolet light of a frequency of 300-400 nanometers. Such compounds and light sources for their curing are described in Dymax MD selector guide, Dymax data sheets and the Dymax 10M catalog.

Instead of the first proximal occlusion catheter 6 shown in Figures 7 and 8 and comprising two guide wire tubes 9, use can also be made of a proximal occlusion catheter 6 comprising only one guide wire tube. It is indeed possible to draw the two guide wires 1 through one and the same guide wire tube but, in view of obtaining a good sealing between the blood channel forming catheters 33 and the proximal occlusion catheter 6 and especially in view of the shape of the finally

obtained entrance to the new blood channels 41, it is preferred to use such a proximal occlusion catheter with one single guide wire tube only in case that only one new blood channel has to be formed, i.e. in case a long neck and a non-dilated distal portion of the aorta is still available. A particular embodiment of such a proximal occlusion catheter 6 has been shown in Figures 10 and 11. In this embodiment, a central guide wire tube 9 is surrounded by a first tubular balloon 44 which is itself surrounded by a second tubular balloon 45. The outer side of the second balloon 45 is also glued or afixed to the expandable distal extremity 12 of the inner sheath 8, and is impermeable and has moreover a soft tip 46 so as to obtain the desired "bubble" or "pear" shape and to protect against aorta wall damage. A similar "umbrella" occlusion structure is thus obtained as in the embodiment shown in Figures 7 and 8.

In case only one single new blood channel has to be formed in the aneurysm, it is also possible to replace the proximal occlusion catheter 6 by proximal occluding means provided on the blood channel forming catheter 33 itself. Such an embodiment has been shown in Figure 12. In this embodiment, a second expandable, inflatable portion or balloon 47 has been provided on the blood channel forming catheter 33, more particularly distally with respect to the first balloon 36. The second balloon 47 has a larger diameter than the first balloon 36 and is arranged to be inflated within the proximal neck of the aneurysm 4. It is preferably connected through a separate lumen of the blood channel forming catheter 33 to a valve fitting (not shown) so as to enable to inflate the first balloon 36 under a different pressure and separate to that of the second balloon 47. With the use of a lower inflation pressure, this first balloon 36 may not become stuck in the central lumen 32 of the injection sheath 28 and the inner wall of this injection sheath 28 has not to be reinforced excessively.

In the embodiment shown in Figure 12, the first and second balloons 36 and 47 are fixed to one another, in particular through the intermediary of a diaphragm 48 made of a more rigid material. In this way, the distal extremity of the first balloon 36 is pulled outwards so as to form also a funnel-shaped entrance to the new blood channel 41 which will be formed in the aneurysm 4.

The embodiment shown in Figure 12 is especially to be preferred in case blood vessel sections which are not aneurysmal, but which are damaged as a result of for example the intravascular dilatation of a blood vessel occlusion or a trauma such as a bullet or a knife wound or which comprise an AV fistula, are to be repaired. In such cases, the diameter of the second balloon 47 may be larger than the diameter of the first balloon 36 but not necessarily. Both diameters may for example be equal. The second balloon 47 may even be omitted since it is even possible to occlude the blood vessel at the proximal side of the damaged section by means of the distal portion of the first balloon 36 itself.

In another embodiment, shown in Figure 13, the proximal occlusion means can be inserted also from below and enable moreover to form a double new blood channel within the aneurysm. This embodiment may be advantageous in case the upper blood vessels are too narrow or in case a very quick intervention is required. Referring to Figure 13, the proximal occlusion means comprise an occlusion balloon 50 mounted on a distal extremity of a guide wire tube 51. This occlusion balloon 50 and guide wire tube 51 can be inserted, over a guide wire 1, upwards through the aneurysm into the non-dilated part of the aorta with or without the use of an additional release sleeve.

In order to be able to apply a second guide wire 1 through the proximal occlusion means, the occlusion balloon 50 defines a funnel-shaped cavity 51 around the distal extremity of the guide wire tube 51. In the bottom of this funnel-shaped cavity 52, i.e. at the distal end of the

guide wire tube 51, is provided an opening 53 for the second guide wire 1. For making it easier to insert the guide wire 1 into the funnel-shaped cavity 52, use can be made of a guiding sheath 54 which is introduced over the guide wire tube 51 and shows at its distal extremity a gutter-shaped profile 55 fitting into the funnel-shaped cavity 52.

As shown in the cross-sectional views of Figures 14 and 15, the balloon 50 is connected by means of a diaphragm 56 having an appropriate width to the guide wire tube 51. This diaphragm comprises more particularly a cross-channel (not shown) connecting the interior of the balloon 50 to an inflation lumen provided around the guide wire tube 51 by a sleeve 74 arranged therearound. This sleeve 74 has not been shown in Figures 14 and 15 but only in the variant embodiment shown in Figure 16.

In this variant embodiment, the occlusion balloon consists of a first, more elongated balloon 57 surrounded by a second, shorter balloon 58. An advantage of such a double balloon structure is that a more stable structure can be obtained and that the inner balloon can be inflated hereto for example to a higher pressure than the outer balloon. For inflating the outer balloon 58, the inner balloon 57 may be provided with a porous, pressure sensitive wall or alternatively, the diaphragm 56 may extend through the inner balloon 57 up to the outer balloon 58, as shown in the cross-sectional view of Figure 17, and may be provided with a further channel for inflating the outer balloon 58. This channel may be connected either by a same or by a different inflation lumen to a source of pressurised fluid, but this has not been shown in the drawings.

Figure 18 shows a modification which can be applied to the distal occlusion catheter 21 shown in Figures 4 to 6. In this modified embodiment the sheath 22 of this occlusion catheter 21 is provided with one or more apertures 59 providing a passageway for the flow of blood material out of the aneurysm 4, between the sheath 22 and the injection

sheath 28 (not shown in Figure 18), into the blood vessel distally with respect to the aneurysm 4. In this way, loss of blood can be restricted to a minimum. The occlusion catheter 21 comprises in this embodiment a second sheath 60 which is slidably disposed over the first sheath 22 more particularly between a first position wherein it closes off said aperture(s) 59 and a second position wherein it opens said aperture(s) 59. In its most distal position, it may moreover cover the occlusion balloon 23 itself, for example when inserting the occlusion catheter 21. In an alternative embodiment, the second sheath 60 could be provided with aperture(s) corresponding to the aperture(s) in the first sheath 22 and could be mounted in particular rotatably on the first sheath 22 so as to enable to bring the apertures into and out of alignment with one another. On the other hand, the second sheath 60 could also be disposed within the first sheath 22.

A possible variant embodiment of the injection means is shown in Figures 19 and 20. In this embodiment, the injection sheath 28 is provided with two series of injection openings, namely distal openings 62 for injecting a first occluding agent in the aneurysm 4 and still somewhat more distal openings 63 for injecting a second occluding agent therein. The second occluding agent is more particularly injected within the mass formed by the reacting first occluding agent so that the wall of the newly formed blood channel will consist of two different layers. For the delivery of the two occlusion agents, the injection sheath 28 comprises two occlusion agent delivery lumens 64, 65 each connected to a separate inlet port 66, 67 at the proximal extremity.

For getting a better distribution of the occluding agent(s) in the aneurysm, even with less injection openings, the injection means illustrated in Figure 19 comprise a motor 68 for rotating the injection sheath 28 around its longitudinal axis, the inlet ports 66, 67 being maintained stationary. The motor 68 may further drive a counter gear

wheel 69 screwed on a threaded rod 70 fixed between a flange 71 on the proximal extremity of the occlusion catheter 21 and a flange 72 fixed to flange 71 by means of threaded rod 70 and one or more further rods 73 to which the motor 68 may also be slidably connected. Due to the simultaneous rotation of counter gear wheel 69 the injection sheath 28 is automatically withdrawn when injecting the occluding agent(s).

In a variant embodiment, one of the occlusion agent delivery lumens 64, 65 may be arranged to deliver a skeleton material, in particular a supporting wire of a shape memory alloy as disclosed for example in US-A-4,512,338 (Balko et al.) or another synthetic or polymeric substance, around the blood channel forming catheter in the blood vessel section. It is also possible to provide a further lumen therefor in the injection sheath 28. The inserted wire or wires may provide an immediate support and encourage the formation of a solid mass upon contact with the occluding agent. In other words, it enables to deliver an immediate and custom made internally supported endograft.

With respect to the dimensions of the different catheters of the arrangement according to the invention, it should be noted that the diameters thereof can be kept to a minimum, especially in case no graft is to be positioned in the aneurysm. In the embodiment shown in Figures 1 to 9, the following diameters can for example be applied :

| | Outer diameter |
|---|---|
| Proximal occlusion catheter | 16-18 FR (5.3-6 mm) |
| Distal occlusion catheter | 16-18 FR (5.3-6 mm) |
| Injection sheath | 14-16 FR (4.7-5.3 mm) |
| Blood channel forming catheter | 5-9 FR (1.67-3 mm) |

In order to monitor the different operations carried out within the patient, radiopaque markers are preferably provided on the different sheaths and on the tips of the guide wire tubes 9 and the blood

channel forming catheters 33. Moreover, the outer surface of the injection sheath 28 is provided with calibrated markers 49 so that, once inserted, the length of the new blood channel which is to be formed can be determined and, just before inserting the blood channel forming catheter 33, the aortic endografts, if used, can be cut to the required length so that no prior measurements have to be done and so that a quick intervention is possible.

From the above description, it will be clear that many modifications can still be applied to the described embodiments without departing from the scope of the annexed claims.

## CLAIMS

1. An arrangement for the endovascular repair of a blood vessel section wherein a new blood channel wall is formed in this section, characterized in that it comprises:

- means for isolating said section, including distal occluding means for occluding the blood vessel at a distal end of said section and proximal occluding means for occluding the blood vessel at a proximal end thereof;
- a blood channel forming catheter arranged for being inserted into said section to define a blood channel within said section between said proximal and distal occluding means; and
- means for injecting an occluding agent producing a solid mass in said section around said blood channel forming catheter to form said new blood wall around said blood channel.

2. An arrangement according to claim 1, characterized in that said blood channel forming catheter comprises a first expandable, inflatable portion arranged to define in its expanded state said blood channel.

3. An arrangement according to claim 1 or 2, characterized in that said blood channel forming catheter is arranged for carrying on its outer surface an endoluminal graft, in particular a balloon or self-expandable endograft, and for disposing this endograft between said proximal and distal occluding means in said section to form part of said new wall, in particular the inside thereof.

4. An arrangement according to any one of the claims 1 to 3, characterized in that said means for injecting an occluding agent comprise an injection sheath which is insertable through said distal occluding means, in particular said occluding means, and which has a lumen arranged to slidably house said blood channel forming catheter.

5. An arrangement according to claim 4, characterized in that said injection sheath is provided near its distal extremity with one or more occluding agent injection openings.

6. An arrangement according to claim 4 or 5, characterized in that said means for injecting an occluding agent comprises means, in particular a motor or a rotational device, for rotating said injection sheath around its longitudinal axis.

7. An arrangement according to any one of the claims 4 to 6, characterized in that said injection sheath comprises at least two lumens with one or more distal openings arranged for injecting respectively a first and a second occluding agent in said section, one outside the other, to form a wall consisting of at least two different layers.

8. An arrangement according to any one of the claims 4 to 7, characterized in that said injection sheath comprises a further lumen arranged for inserting a skeleton material, in particular a supporting metal wire, with or without shape memory or a synthetic or polymeric supporting structure, around said blood channel forming catheter in said section.

9. An arrangement according to any one of the claims 1 to 8, characterized in that said proximal occluding means comprise a first occlusion catheter including an outer sheath, an inner sheath having an expandable substantially impermeable distal extremity, in particular a self-expandable or balloon-adjustable distal extremity comprising a reinforcement of a substantially inelastic material, which can be slid out of said outer sheath to occlude the proximal end of said section, a guide wire tube disposed in said inner sheath and at least one inflatable balloon chamber disposed between said guide wire tube and said inner sheath to urge the distal extremity of the inner sheath against the wall of the blood vessel upon inflation of said balloon chamber, said balloon

chamber projecting in particular beyond the extremity of the guide wire tube and the edge of the inner sheath.

10. An arrangement according to claim 9, characterized in that said first occlusion catheter comprises a further guide wire tube and a further inflatable balloon chamber connected at the distal extremity of the balloon catheter to the guide wire tubes so as to separate them upon inflation of this further balloon chamber.

11. An arrangement according to any one of the claims 1 to 8, characterized in that said proximal occluding means are provided on said blood channel forming catheter.

12. An arrangement according to claims 2 and 11, characterized in that said proximal occluding means are formed by a distal portion of said first expandable inflatable portion of the blood channel forming catheter.

13. An arrangement according to claims 2 and 11, characterized in that said proximal occluding means comprise a second expandable, inflatable portion located distally on said blood channel forming catheter with respect to said first expandable, inflatable portion.

14. An arrangement according to claim 13, characterized in that said first and second expandable, inflatable portions are fixed to one another, in particular through the intermediary of an expandable or foldable separation diaphragm of a substantially inelastic material.

15. An arrangement according to any one of the claims 1 to 8, characterized in that said proximal occluding means comprise an occlusion balloon mounted on a distal extremity of a guide wire tube for a first guide wire and defining a funnel-shaped cavity around this guide wire tube, which funnel-shaped cavity has its smallest diameter at its distal end and is provided at this distal end next to said guide wire tube with an opening defining a passageway for a second guide wire.

16. An arrangement according to any one of the claims 1 to 15, characterized in that said distal occluding means comprise a second occlusion catheter including at least a first sheath and an expandable, inflatable occlusion balloon provided thereon, in particular at its distal end.

17. An arrangement according to claim 16, characterized in that said second occlusion catheter comprises a passageway including an aperture in said first sheath for allowing flow of blood material out of said section into the blood vessel distally with respect to said section, and a second sheath movably disposed over or in said first sheath between a first position wherein it closes off said aperture and a second position wherein it opens this aperture.

18. A method for the endovascular repair of a blood vessel section wherein a new blood channel wall is formed in this section, comprising the steps of:

- isolating the blood vessel section including occluding the blood vessel at a distal and at a proximal end of said section;
- inserting a blood channel forming catheter into said section to define a blood channel therein;
- injecting an occluding agent around said blood channel forming catheter in said section;
- allowing said occluding agent to harden to form said new blood channel wall; and
- removing the blood channel forming catheter and the distal and proximal occlusions provided in the blood vessel.

19. The method as claimed in claim 18, wherein said occluding agent is injected through an injection sheath, wherein said blood channel forming catheter comprises an expandable, inflatable portion arranged to define in its expanded state said blood channel in said section, and wherein during injection of the occluding agent through

the injection sheath, the injection sheet is gradually withdrawn and said expandable, inflatable portion is inflated to form said blood channel.

20. The method as claimed in claim 18, wherein a balloon or self-expandable endograft is applied onto the blood channel forming catheter before insertion thereof through the distal occlusion, either with or without the use of a supplementary release sheath.

21. The method as claimed in claim 20, wherein said occluding agent is injected through an injection sheath onto which calibrated markers are provided to determine the length of the new blood channel wall which is to be formed, and wherein said endograft is cut off on the basis of the thus determined length.

AMENDED CLAIMS

[received by the International Bureau on 14 July 1998 (14.07.98); original claims 1-21 replaced by new claims 1-23 (5 pages)]

1. An arrangement for the endovascular repair of a blood vessel section wherein a new blood channel wall is formed in this section, characterized in that it comprises:

- means for isolating said section, including distal occluding means for occluding the blood vessel at a distal end of said section and proximal occluding means for occluding the blood vessel at a proximal end thereof, said distal occluding means comprising at least one distal occlusion catheter with a lumen ;
- at least one blood channel forming catheter arranged for being inserted through the lumen of said distal occlusion catheter into said section to define a blood channel within said section between said proximal and distal occluding means; and
- means for injecting an occluding agent producing a solid mass in said section around said blood channel forming catheter to form said new blood wall around said blood channel.

2. An arrangement according to claim 1, characterized in that said blood channel forming catheter comprises a first expandable, inflatable portion arranged to define in its expanded state said blood channel.

3. An arrangement according to claim 1 or 2, characterized in that said blood channel forming catheter is arranged for carrying on its outer surface an endoluminal graft, in particular a balloon or self-expandable endograft, and for disposing this endograft between said proximal and distal occluding means in said section to form part of said new wall, in particular the inside thereof.

4. An arrangement according to any one of the claims 1 to 3, characterized in that it comprises two blood channel forming catheters whilst said distal occluding means comprise two distal occlusion catheters with a lumen, the two blood channel forming catheters being

each arranged for being inserted through the lumen of one of said distal occlusion catheters into said section to define two blood channels between said proximal and distal occluding means.

5. An arrangement according to any one of the claims 1 to 4, characterized in that said means for injecting an occluding agent comprise an injection sheath which is insertable through said occluding means, in particular through the lumen of said distal occlusion catheter, and which has a lumen arranged to slidably house said blood channel forming catheter.

6. An arrangement according to claim 5, characterized in that said injection sheath is provided near its distal extremity with one or more occluding agent injection openings.

7. An arrangement according to claim 5 or 6, characterized in that said means for injecting an occluding agent comprises means, in particular a motor or a rotational device, for rotating said injection sheath around its longitudinal axis.

8. An arrangement according to any one of the claims 5 to 7, characterized in that said injection sheath comprises at least two lumens with one or more distal openings arranged for injecting respectively a first and a second occluding agent in said section, one outside the other, to form a wall consisting of at least two different layers.

9. An arrangement according to any one of the claims 5 to 8, characterized in that said injection sheath comprises a further lumen arranged for inserting a skeleton material, in particular a supporting metal wire, with or without shape memory or a synthetic or polymeric supporting structure, around said blood channel forming catheter in said section.

10. An arrangement according to any one of the claims 1 to 9, characterized in that said proximal occluding means comprise a first occlusion catheter including an outer sheath, an inner sheath having an

expandable substantially impermeable distal extremity, in particular a self-expandable or balloon-adjustable distal extremity comprising a reinforcement of a substantially inelastic material, which can be slid out of said outer sheath to occlude the proximal end of said section, a guide wire tube disposed in said inner sheath and at least one inflatable balloon chamber disposed between said guide wire tube and said inner sheath to urge the distal extremity of the inner sheath against the wall of the blood vessel upon inflation of said balloon chamber, said balloon chamber projecting in particular beyond the extremity of the guide wire tube and the edge of the inner sheath.

11. An arrangement according to claim 10, characterized in that said first occlusion catheter comprises a further guide wire tube and a further inflatable balloon chamber connected at the distal extremity of the balloon catheter to the guide wire tubes so as to separate them upon inflation of this further balloon chamber.

12. An arrangement according to any one of the claims 1 to 9, characterized in that said proximal occluding means are provided on said blood channel forming catheter.

13. An arrangement according to claims 2 and 12, characterized in that said proximal occluding means are formed by a distal portion of said first expandable inflatable portion of the blood channel forming catheter.

14. An arrangement according to claims 2 and 12, characterized in that said proximal occluding means comprise a second expandable, inflatable portion located distally on said blood channel forming catheter with respect to said first expandable, inflatable portion.

15. An arrangement according to claim 14, characterized in that said first and second expandable, inflatable portions are fixed to one another, in particular through the intermediary of an expandable or foldable separation diaphragm of a substantially inelastic material.

16. An arrangement according to any one of the claims 1 to 9, characterized in that said proximal occluding means comprise an occlusion balloon mounted on a distal extremity of a guide wire tube for a first guide wire and defining a funnel-shaped cavity around this guide wire tube, which funnel-shaped cavity has its smallest diameter at its distal end and is provided at this distal end next to said guide wire tube with an opening defining a passageway for a second guide wire.

17. An arrangement according to any one of the claims 1 to 16, characterized in that said distal occlusion catheter includes a passageway for venting material out of said aneurysm.

18. An arrangement according to claim 17, characterized in that said distal occlusion catheter includes at least a first sheath and an expandable, inflatable occlusion balloon provided thereon, in particular at its distal end, said passageway including an aperture in said first sheath for allowing flow of blood material out of said section into the blood vessel distally with respect to said section, and the distal occlusion catheter comprises further a second sheath movably disposed over or in said first sheath between a first position wherein it closes off said aperture and a second position wherein it opens this aperture.

19. A method for the endovascular repair of a blood vessel section wherein a new blood channel wall is formed in this section, comprising the steps of:

- isolating the blood vessel section including occluding the blood vessel at a distal end of said section, by means of at least one distal occlusion catheter with a lumen, and at a proximal end of said section;
- inserting a blood channel forming catheter through the lumen of said distal occlusion catheter into said section to define a blood channel therein;
- injecting an occluding agent around said blood channel forming catheter in said section;

- allowing said occluding agent to harden to form said new blood channel wall; and
- removing the blood channel forming catheter and the distal and proximal occlusions provided in the blood vessel.

20. The method as claimed in claim 19, wherein said occluding agent is injected through an injection sheath, wherein said blood channel forming catheter comprises an expandable, inflatable portion arranged to define in its expanded state said blood channel in said section, and wherein during injection of the occluding agent through the injection sheath, the injection sheet is gradually withdrawn and said expandable, inflatable portion is inflated to form said blood channel.

21. The method as claimed in claim 20, characterized in that use is made of an injection sheath provided near its distal extremity with one or more occluding agent injection openings in order to fill said blood vessel section from the proximal to the distal extremity thereof with said occluding agent, evacuation of liquid out of said blood vessel section being in particular provided through a passageway in said distal occlusion catheter.

22. The method as claimed in claim 19, wherein a balloon or self-expandable endograft is applied onto the blood channel forming catheter before insertion thereof through the distal occlusion, either with or without the use of a supplementary release sheath.

23. The method as claimed in claim 22, wherein said occluding agent is injected through an injection sheath onto which calibrated markers are provided to determine the length of the new blood channel wall which is to be formed, and wherein said endograft is cut off on the basis of the thus determined length.

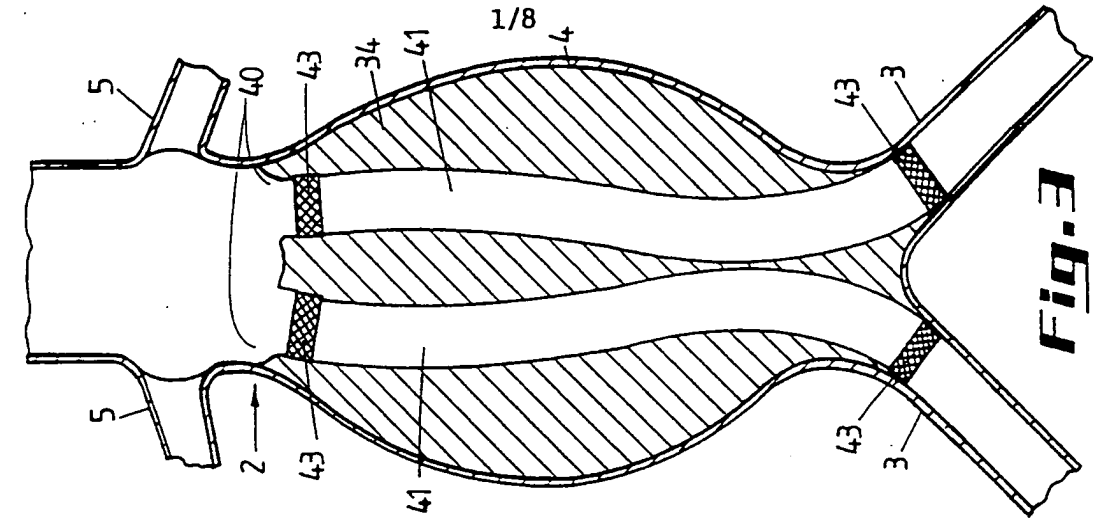


Fig.3

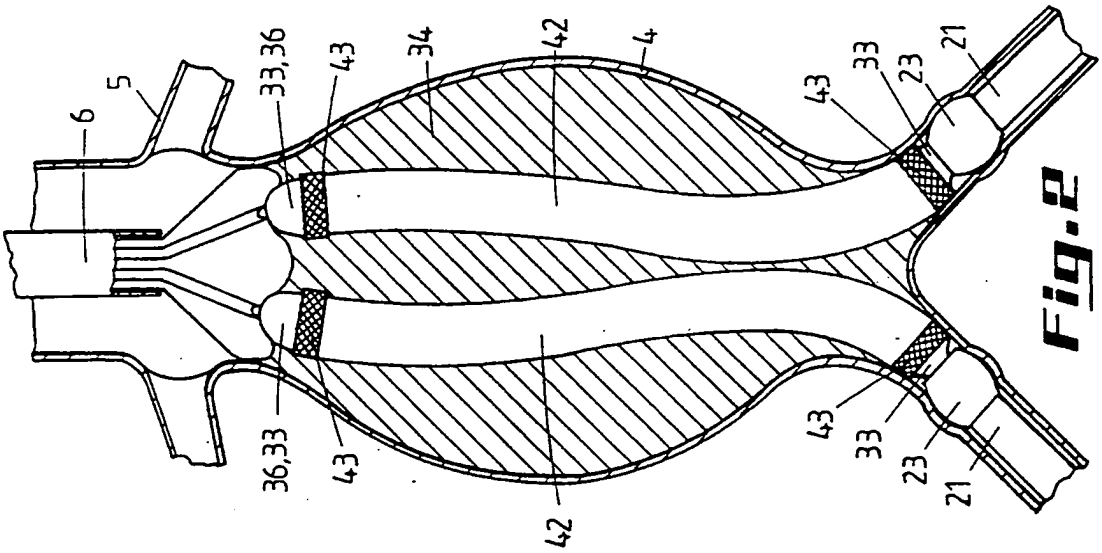


Fig.2

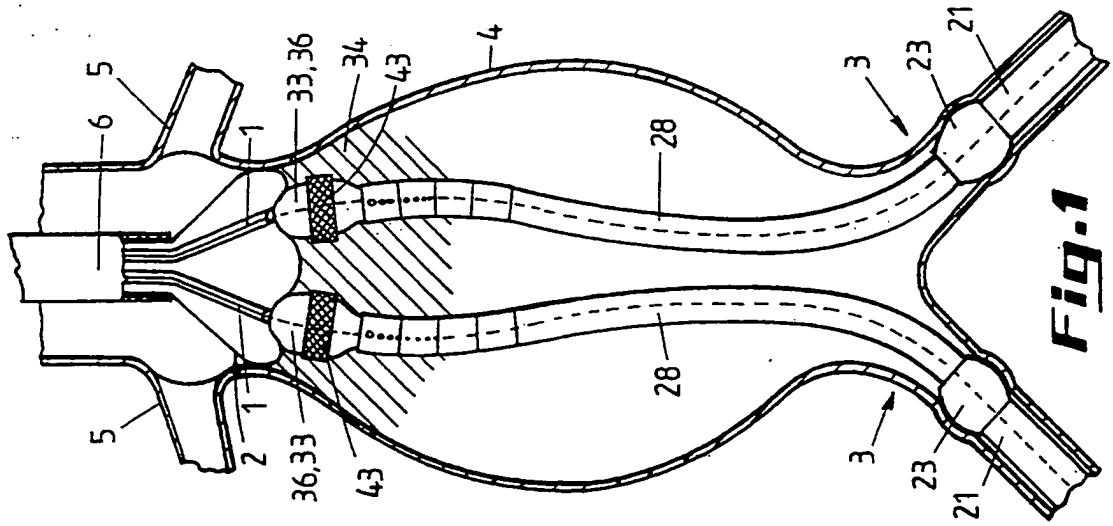


Fig.1

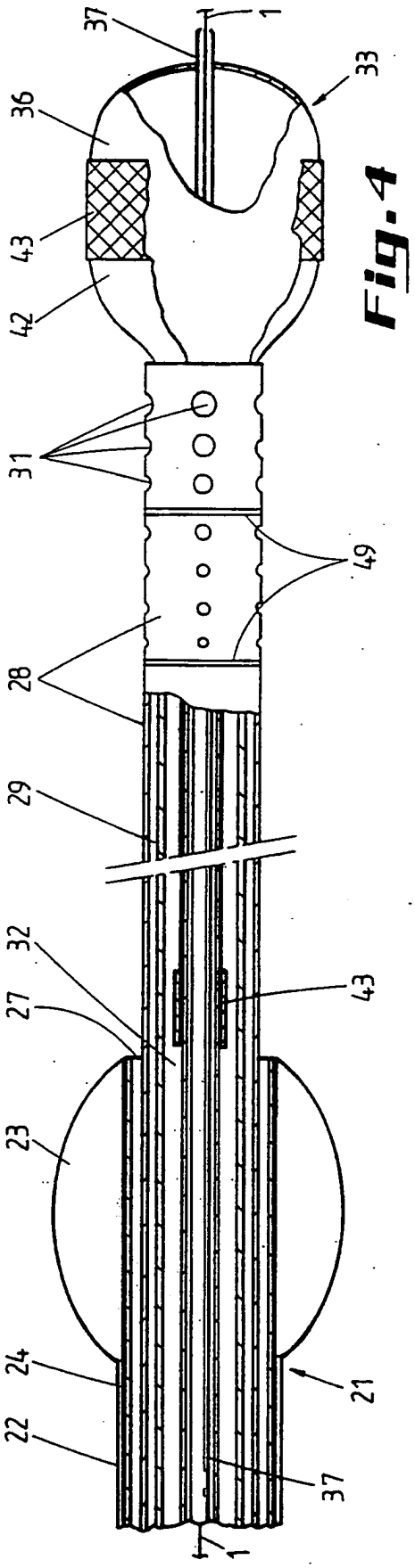
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Fig.4

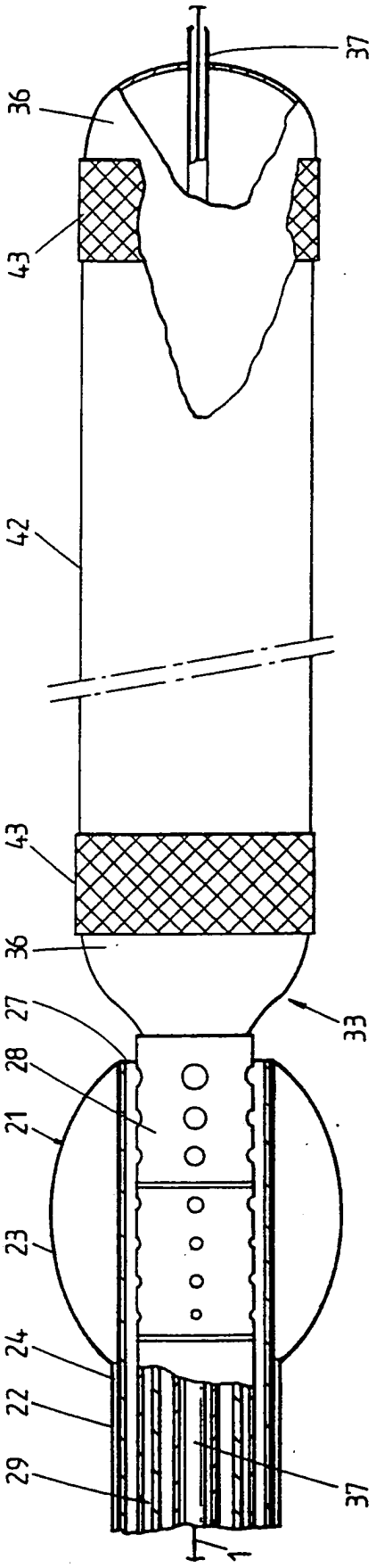
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Fig.5

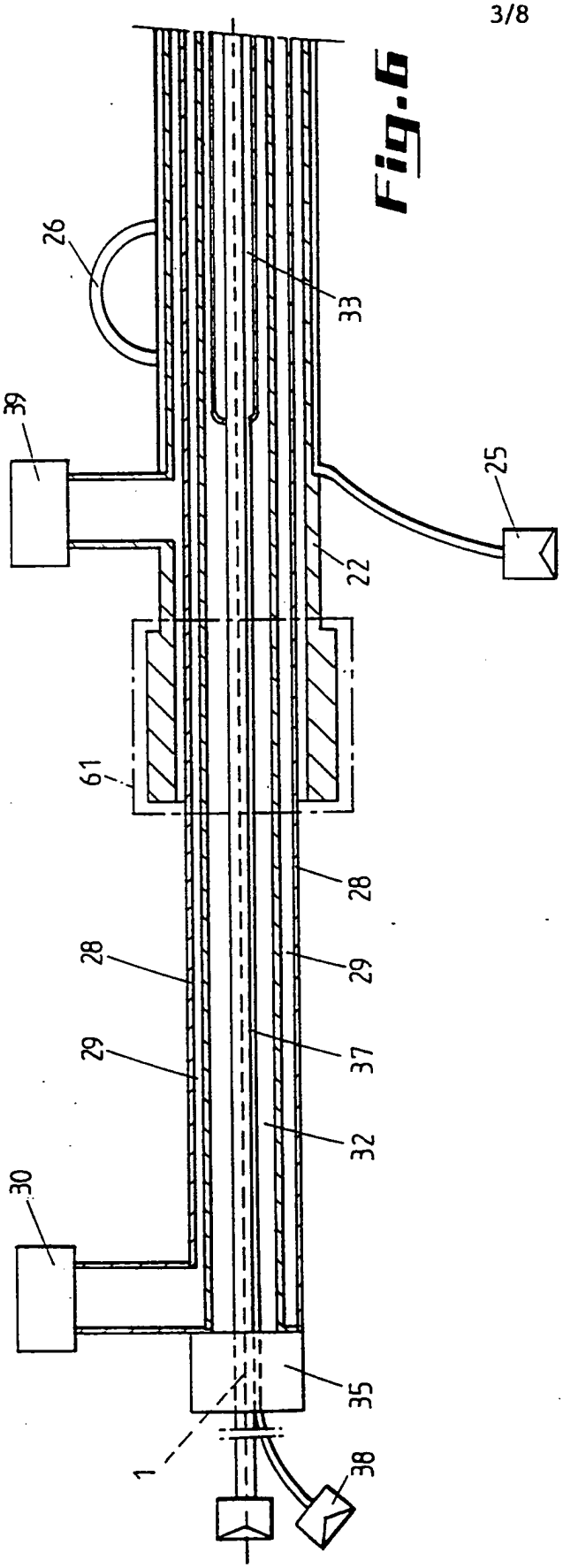
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Fig.6

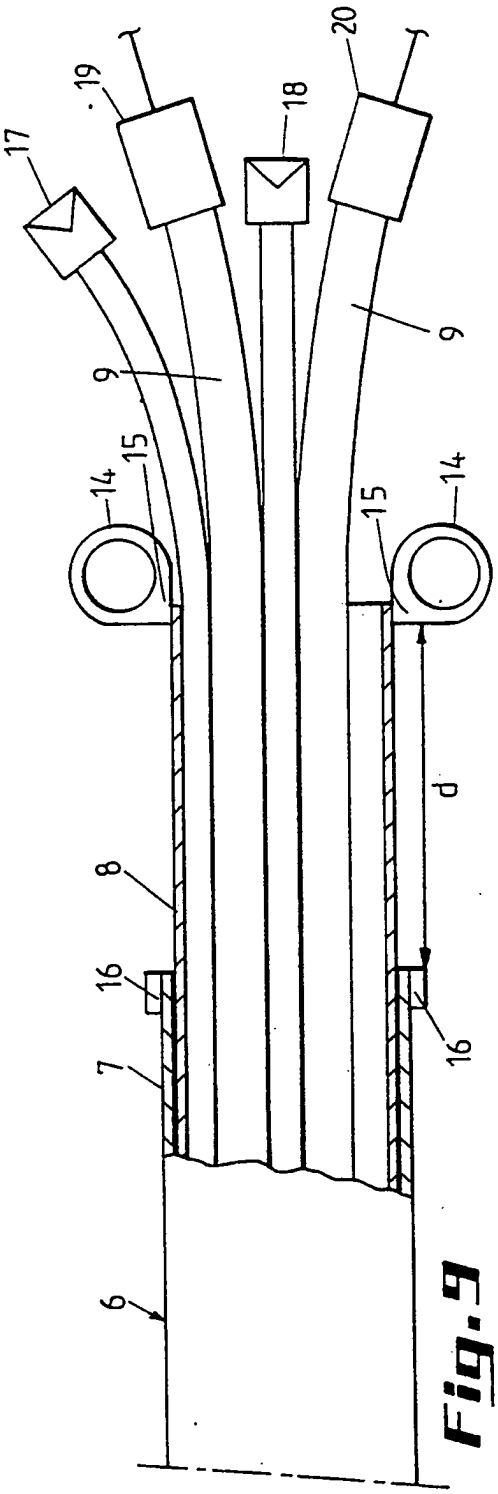
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Fig.9

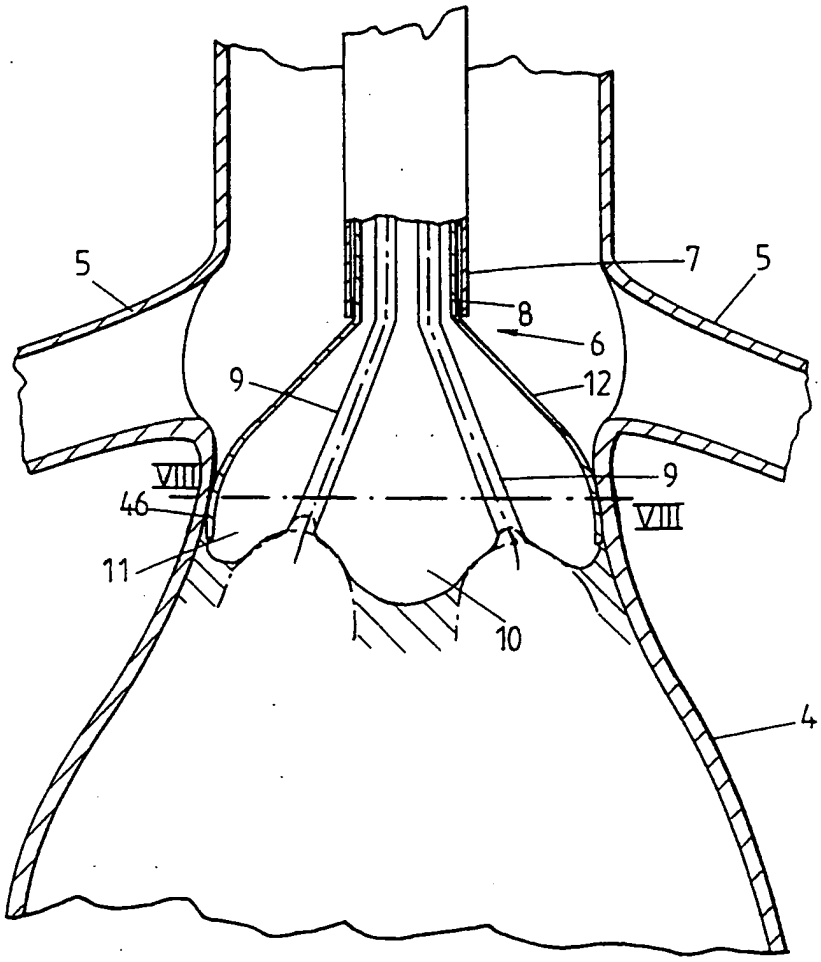


Fig.7

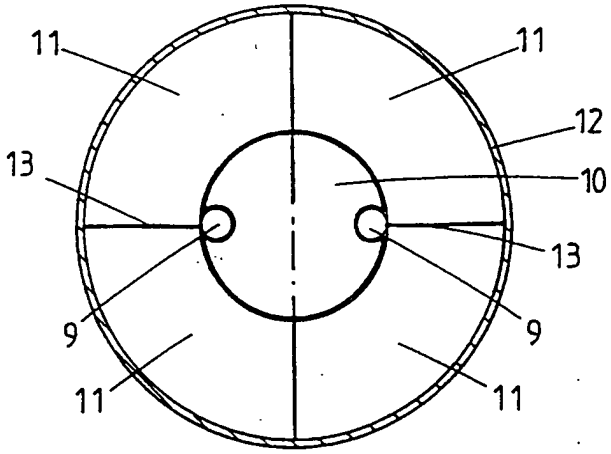


Fig.8

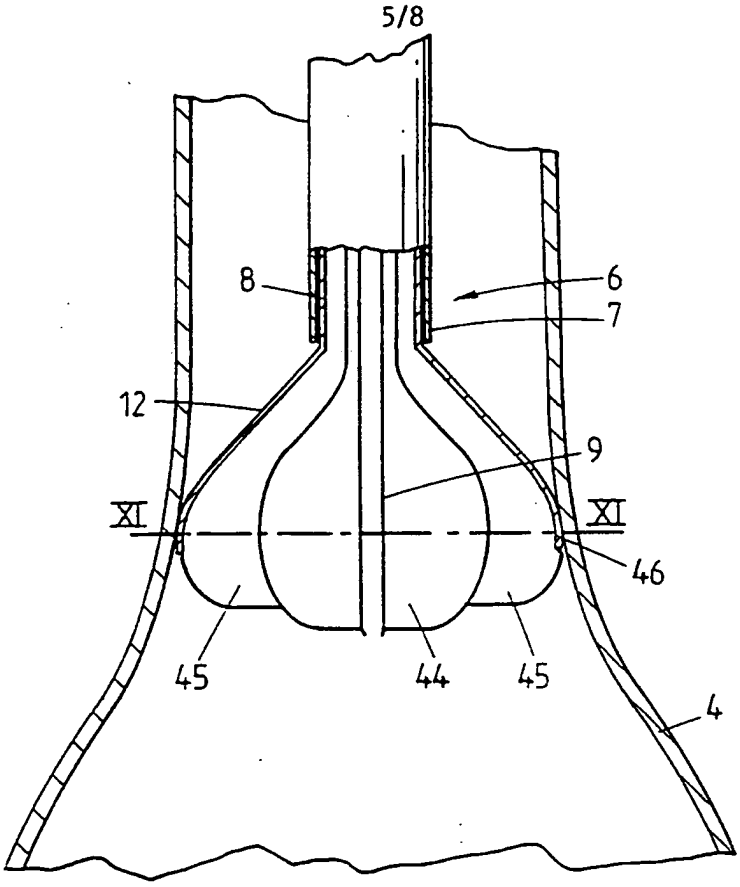


Fig.10

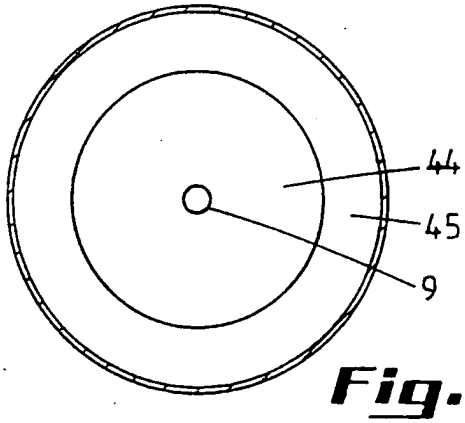


Fig.11

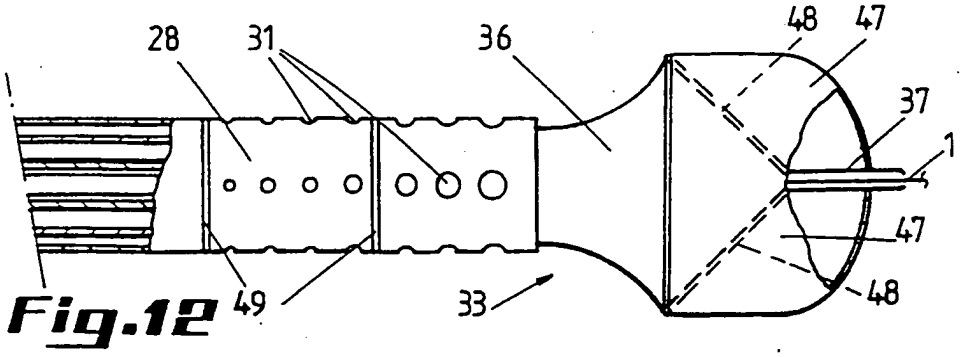


Fig.12

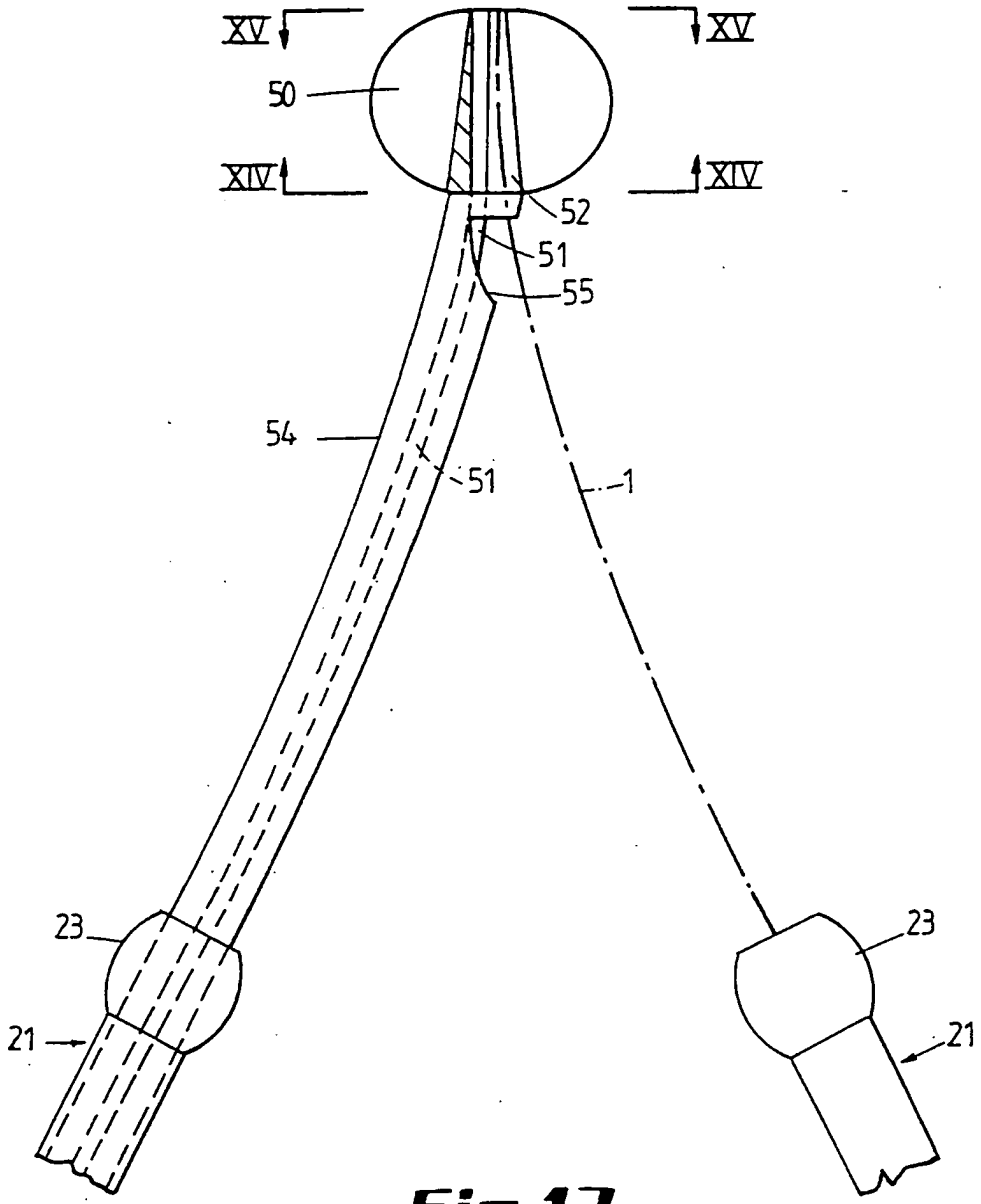


Fig.13

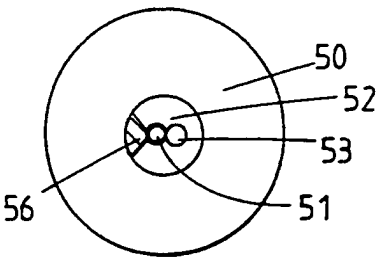


Fig.14

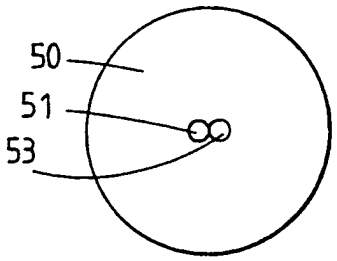


Fig.15

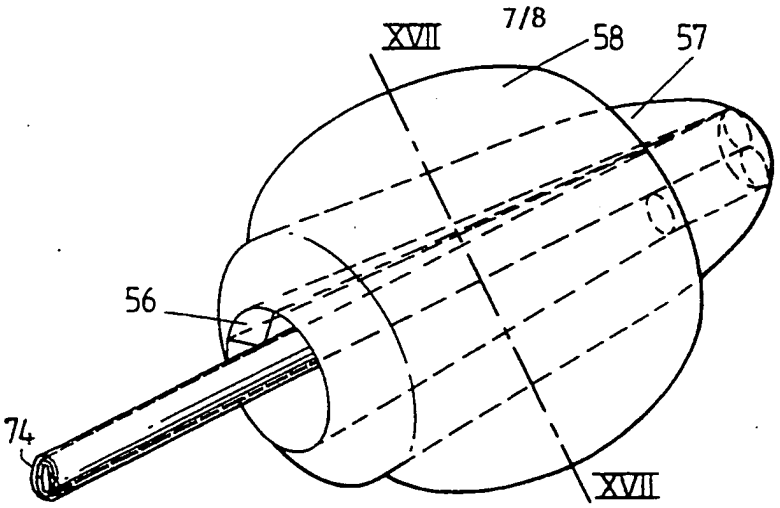


Fig.16

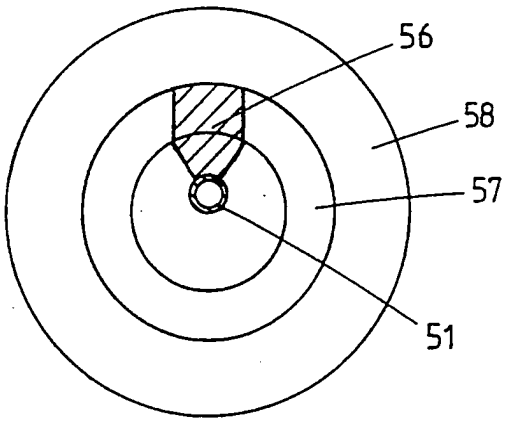


Fig.17

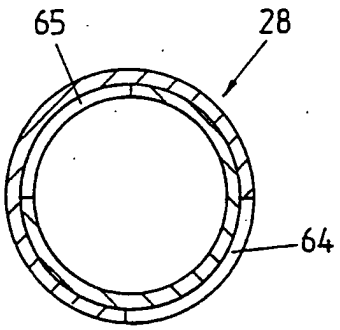


Fig.20

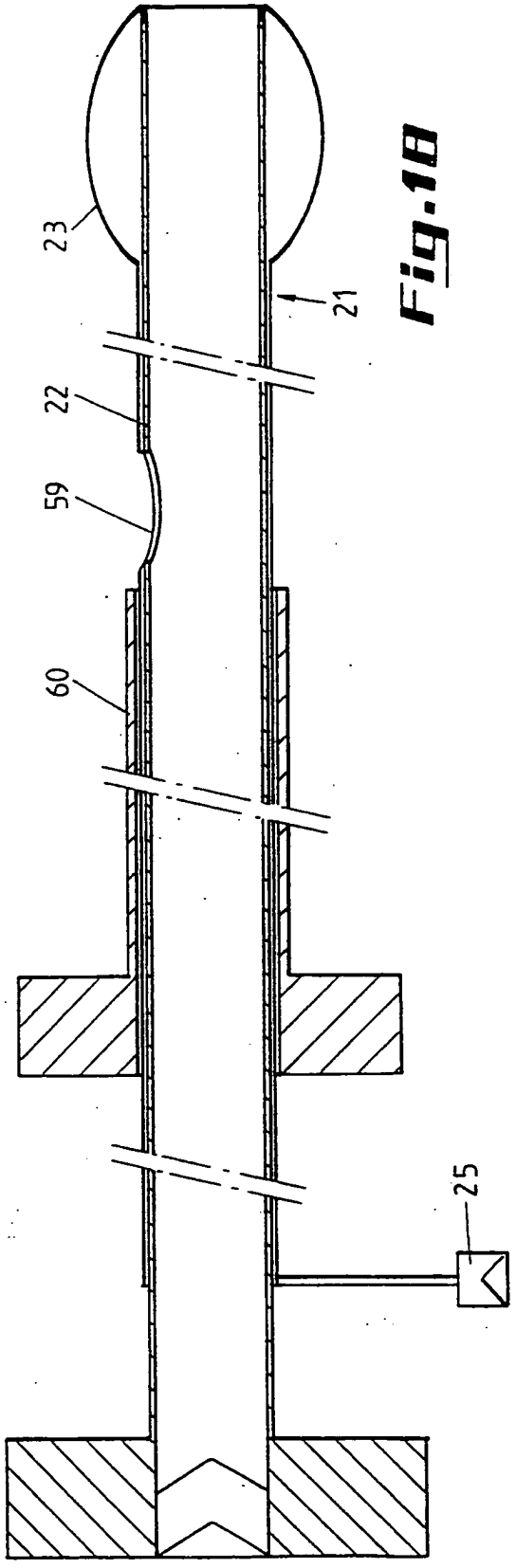


Fig.18

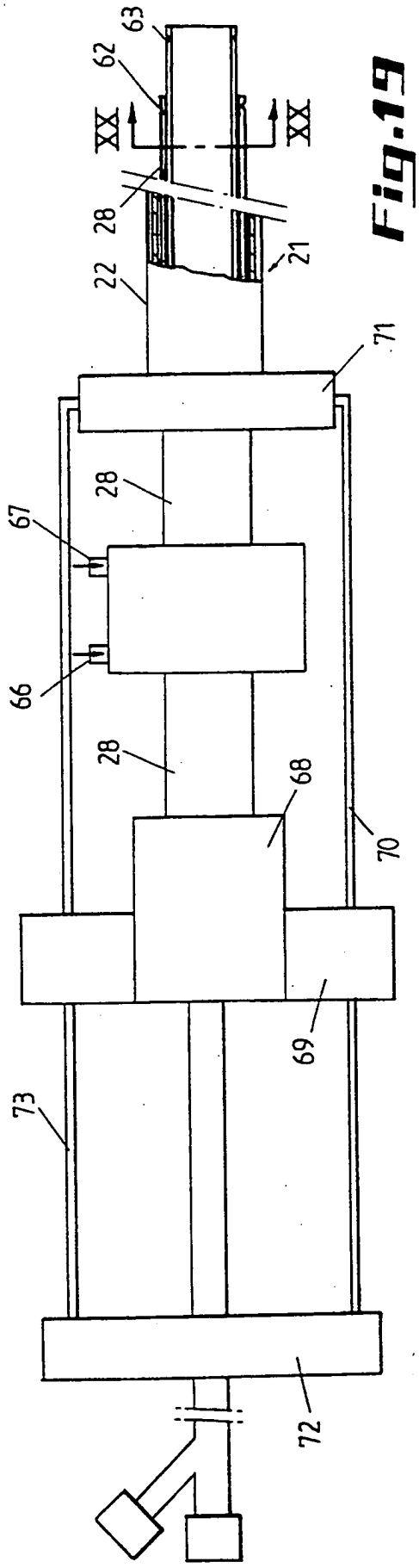


Fig.19

# INTERNATIONAL SEARCH REPORT

Interi .ial Application No
PCT/BE 97/00034

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X<br>Y | WO 97 03717 A (ENDOTEX INTERVENTIONAL SYSTEMS, INC.) 6 February 1997<br>see the whole document | 1,2,<br>11-14<br>3-5,8 |
| Y | WO 97 09008 A (MEDTRONIC, INC) 13 March 1997<br>see the whole document | 3-5,8 |
| A | WO 95 08289 A (SCIMED LIFE SYSTEMS, INC) 30 March 1995 | |
| A | EP 0 664 104 A (MICRO THERAPEUTICS,INC) 26 July 1995<br>cited in the application | |

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

1

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 13 November 1997 | 28. 11. 97 |

| Name and mailing address of the ISA | Authorized officer |
|---|---|
| European Patent Office, P.B. 5818 Patentlaan 2<br>NL – 2280 HV Rijswijk<br>Tel. (+31–70) 340–2040, Tx. 31 651 epo nl,<br>Fax: (+31–70) 340–3016 | Smith, C |

Form PCT/ISA/210 (second sheet) (July 1992)

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/BE 97/00034

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 18-21
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

**Remark on Protest**

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

.ormation on patent family members

Interr ıal Application No
PCT/BE 97/00034

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
|---|---|---|---|
| WO 9703717 A | 06-02-97 | AU 6547096 A | 18-02-97 |
| WO 9709008 A | 13-03-97 | AU 7154796 A | 27-03-97 |
| WO 9508289 A | 30-03-95 | NONE | |
| EP 664104 A | 26-07-95 | CA 2140983 A<br>JP 8033715 A | 25-07-95<br>06-02-96 |